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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,540	02/17/2004	Dipak K. Chowdhury		7483

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EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/780,540

Applicant(s)

CHOWDHURY ET AL.

Examiner

Zohreh Fay

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1614

Claims 1-8 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using tetrahydrocannabinol in treating glaucoma, does not reasonably provide enablement for using tetrahydrocannabinol in preventing glaucoma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method of treating, preventing, ameliorating, lessening or mitigating glaucoma using THC.

2) The state of the prior art:

The prior art does not recognize that the prevention of glaucoma is easily accomplished. According to *LANCE*, Current Medical Diagnosis and Treatment, 43<sup>rd</sup> Edition, page 156, the only prevention for glaucoma is considered to be tonometric and ophthalmoscopic examination every 2 years for the people over the age of 40. Such

Art Unit: 1614

examination is used to determine if a person is having glaucoma. Annual examination for the people with the family history of glaucoma is recommended.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability and unpredictability of the art:

The unpredictability of the pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are drawn to treating, preventing, ameliorating, lessening or mitigating glaucoma using tetrahydrocannabinol. Such claims are considered to be broad in nature.

6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for the treatment of glaucoma. However the specification provides no guidance, to enable one skilled in the art to prevent glaucoma.

7) The presence or absence of working examples:

The examples in applicant's specification are drawn to the use of different polymers in combination with different active ingredient for the treatment of different disorders. Treatment of glaucoma is mentioned in one example. However, there are no examples to demonstrate the "prevention" of glaucoma using tetrahydrocannabinol.

8) The quantity of experimentation necessary:

Art Unit: 1614

Since the examples in the specification are drawn to the treatment of glaucoma, one of ordinary skill in the art would be burdened with undue experimentation to determine the effectiveness of the claim compound in preventing glaucoma.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murty et al. (6,503,532) in view of Watts et al. (6,383,513)

Murty et al. Teach the use of tetrahydrocannabinol in a pharmaceutical formulation in combination with carbopol. See the abstract. The use of methylcellulose is taught in column 2 line 1. The above reference also teaches the use of such compound for the treatment of glaucoma. See column 1, lines 7-11. The primary reference differs from the claimed invention in the presence of a poloxamer. Watts et al. Teach that poloxamer has been previously used in combination with cannabinoids. See the abstract, column 3, lines 38-45 and claim 6. It would have been obvious to a person skilled in the art to incorporate poloxamer into the primary reference considering that Watts et al. teach the addition of such polymer to cannabinoids as old and well known.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of THC in combination with carbopol or methylcellulose in a pharmaceutical formulation and the other relates to the use of THC in combination with poloxamer in a pharmaceutical formulation. The use of

Art Unit: 1614

cannabinoids for the treatment of glaucoma is also taught by Murty et al. The above references make clear that the claimed compound has been previously used in combination with the claim-designated polymers. Murty et al. make clear that cannabiniol has been previously used for the treatment of glaucoma. The determination of optimum proportions or viscosity is considered to be within the skill of the artisan in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-8 are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/780,540  
Art Unit: 1614

Page 6

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10/780,540  
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